John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs/Counterclaim-Defendants AstraZeneca AB, AstraZeneca LP, KBI-E Inc. and Pozen, Inc.

Henry J. Renk
Bruce C. Haas
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER& SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and KBI-E Inc.

Stephen M. Hash
Stephen C. Stout
Deirdre Dorval
Shannon Kidd
VINSON & ELKINS LLP
2801 Via Fortuna, Suite 100
Austin, TX 78746-7568
(512) 542-8400

Of Counsel for Plaintiff Pozen Inc.

Einar Stole
Edward H. Rippey
Maureen M. Japha
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and KBI-E Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN, INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Defendants.	Civil Action No. **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.**

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 202654 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' VIMOVO® pharmaceutical products that are sold in the United States.

THE PARTIES

2. Plaintiff AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff KBI-E Inc. ("KBI-E") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware.

5. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

6. On information and belief, Defendant Lupin Ltd. ("Lupin Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at B/4 Laxmi

Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

7. On information and belief, Defendant Lupin Pharmaceuticals Inc. ("Lupin Inc.") is a corporation operating and existing under the laws of the Commonwealth of Virginia, with its principal place of business at 111 South Calvert Street 21st Floor, Baltimore, MD 21202.

8. On information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Ltd.

BACKGROUND

The NDA

9. AZ LP is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

10. VIMOVO® is a prescription drug approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO®.

The Patent-In-Suit

11. United States Patent No. 8,557,285 ("the '285 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 15, 2013. The claims of the '285 patent

are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen. A true and correct copy of the '285 patent is attached as Exhibit A.

12. Pozen owns the '285 patent by assignment from the inventor John R. Plachetka. AZ AB is Pozen's exclusive licensee under the '285 patent. The '285 patent will expire on May 31, 2022.

13. The '285 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the VIMOVO® drug product.

14. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Pozen and the AstraZeneca Plaintiffs are submitting patent information for the '285 patent to the FDA in connection with their NDA No. 022511 for VIMOVO® drug product. The FDA is expected to publish the same in the Orange Book.

The ANDA

15. On information and belief, Lupin Ltd. filed ANDA No. 202654 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for Lupin Ltd. and Lupin Inc. to commercially manufacture, use, import, offer for sale, and sell in the United States naproxen and esomeprazole magnesium delayed release tablets containing 375 mg (naproxen)/20 mg (esomeprazole magnesium) or 500 mg naproxen (naproxen)/20 mg (esomeprazole magnesium) ("Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets" or the "ANDA Products"), which are generic versions of Plaintiffs' VIMOVO® Delayed Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

16. By letter dated June 10, 2011 (the "ANDA Notice Letter"), Lupin Ltd. notified Plaintiffs that it had filed ANDA No. 202654 seeking approval to market Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets and was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

JURISDICTION AND VENUE

17. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

18. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing pharmaceutical products.

19. On information and belief, Lupin Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

20. On information and belief, Lupin Inc., with the assistance and/or at the direction of Lupin Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

21. On information and belief, Defendants acted in concert to develop Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, and to seek approval from the FDA to sell Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets throughout the United States, including within this judicial district.

22. On information and belief, both Lupin Ltd. and Lupin Inc. have been and are engaging in activities directed toward infringement of the '285 patent (the "patent-in-suit") by,

inter alia, preparing and/or submitting ANDA No. 202654 seeking FDA approval to market Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets. As stated in the ANDA Notice Letter, Defendants intend to market Lupin's Naproxen and Esomeprazole Magnesium Delayed Release Tablets before expiration of the patent-in-suit. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 202654 from Lupin Ltd.

23. In its ANDA Notice Letter, Lupin Ltd. stated that the name and address of its agent in the United States authorized to accept service of process for Defendants for purposes of an infringement action based upon its ANDA Notice Letter is Robert F. Green of Leydig, Voit and Mayer Ltd., 180 North Stetson, Suite 4900, Chicago, IL 60601.

24. Upon information and belief, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Inc., has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. Upon information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Inc., manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Lupin Ltd. is subject to personal jurisdiction in New Jersey on the basis of its inducement of and/or contribution to Lupin Inc.'s acts of infringement in New Jersey. In addition, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Lupin Inc. and therefore the activities of Lupin Inc. in this jurisdiction are attributed to Lupin Ltd.

25. On information and belief, this Court has personal jurisdiction over Lupin Inc. because Lupin Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. Upon information and belief, Lupin Inc. manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

26. On information and belief, Lupin Inc. is registered to do business in New Jersey (business identification number 0100953673) and has appointed National Registered Agents, Inc., located at 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for the receipt of service of process.

27. On information and belief, both Lupin Ltd. and Lupin Inc. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., AstraZeneca AB et al. v. Lupin Ltd. et* al, Civ. Action No. 3:11-cv-04275-JAP-DEA (D.N.J.); AstraZeneca *AB et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 3:09-cv-05404-JAP-TJB (D.N.J.); *Abbott Labs and Laboratoires Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01007-GEB-MCA (D.N.J.); *Abbott Labs and Laboratoires Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:10-cv-01578-DMC-JAD (D.N.J.); *Tibotec Inc. and Tibotec Pharm. v. Lupin Ltd., et al.*, Civ. Action No. 2:10-cv-05954-WHW-MAS (D.N.J.); *Novartis Corp. et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:06-cv-05954-GEB-ES (D.N.J.); and *Elan Int'l. Ltd. and Fournier Laboratories Ireland Ltd.*, Civ. Action No. 2:09-cv-01008-GEB-MCA (D.N.J.).

28. On information and belief, Lupin Ltd. and Lupin Inc. have availed themselves of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Lupin Ltd. and Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp.*, Civ. Action No. 3:10-CV-683-JAP-TJB (D.N.J.).

29. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 202654, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

30. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

COUNT I
(INFRINGEMENT OF THE '285 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

31. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

32. On information and belief, the making, using, selling, and/or offering for sale in the United States of Defendants' pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen described in Defendants' ANDA infringes the '285 patent.

33. Defendants have infringed the '285 patent under 35 U.S.C. § 271 (e)(2) by filing their ANDA and continuing to seek approval from the FDA to engage in the commercial manufacture, use, or sale of a drug claimed in this patent, prior to the expiration of the '285 patent.

34. On information and belief, the ANDA Products contain the pharmaceutical composition patented in the '285 patent, constitute a material part of the inventions of the '285 patent, are especially made or especially adapted for use in an infringement of the '285 patent,

and are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '285 patent.

35. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 202654 seeking, *inter alia*, FDA final approval prior to November 27, 2014. The '285 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of their ANDA No. 202654 prior to the expiration date of the '285 patent.

36. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in thier pending ANDA No. 202654 with respect to the '285 patent, and Defendants must make a Paragraph IV Certification with respect to the '285 patent if Defendants continue to seek FDA final approval of their ANDA No. 202654 prior to May 31, 2022. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '285 Patent under 35 U.S.C. § 271(e)(2).

37. On information and belief, the manufacture, use, and sale of the ANDA Products infringes the '285 patent claims.

38. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the patent-in-suit are valid and enforceable;

B. A judgment that the submission of ANDA No. 202654 by Defendants infringes one or more claims of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 202654 shall be no earlier than the later of the expiration date of the patent-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 202654 no earlier than the later of the expiration date of the patent-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: October 23, 2013

Respectfully Submitted,

By: *s/ John E. Flaherty*

John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
ASTRAZENECA AB,
ASTRAZENECA LP, POZEN, INC. and
KBI-E INC.

Of Counsel:
Henry J. Renk
Bruce C. Haas
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER
& SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
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COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
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Stephen M. Hash
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Shannon Kidd
VINSON & ELKINS LLP
2801 Via Fortuna, Suite 100
Austin, TX 78746-7568
(512) 542-8400

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

ASTRAZENECA AB et al. v. DR. REDDY'S LABS. INC., et al., C.A. No. 3:11-cv-02317-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:13-cv-00091-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. ANCHEN PHARMS., INC., C.A. No. 3:11-cv-06348-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC.- FLORIDA, et al., C. A. No. 3:13-cv-03038-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-JAP-DEA (D.N.J.)

ASTRAZENECA AB, et al. v. MYLAN LABORATORIES LTD. et al., C.A. No. 3:12-cv-01378-JAP-TJB (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC. - FLORIDA et al., C.A. No. 3:13-cv-01669-JAP-TJB (D.N.J.); and

ASTRAZENECA AB et al. v. WOCKHARDT LIMITED et al., C.A. No. 3:13-cv-04854-JAP-TJB (D.N.J.)

The foregoing cases involve products that contain an esomeprazole magnesium formulation. The matter in controversy involves the same esomeprazole magnesium formulations. All of these cases have been assigned to Hon. Joel A. Pisano, U.S.D.J. The DRL, Lupin, and Anchen cases have been consolidated for discovery purposes and have been assigned to Magistrate Judge Arpert.

Therefore, for the sake of judicial economy and with regard to Judge Pisano's and Judge Arpert's familiarity of the patents asserted in the matter in controversy, Plaintiffs believe these

cases and the matter in controversy are all related. Accordingly, Plaintiffs respectfully request that the matter in controversy be assigned to Judge Pisano and Magistrate Judge Arpert.

Dated: October 23, 2013

Respectfully Submitted,

By: *s/ John E. Flaherty*

John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
ASTRAZENECA AB,
ASTRAZENECA LP, KBI-E INC,
And Pozen, Inc.

Of Counsel:
Henry J. Renk
Bruce C. Haas
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER & SCINTO
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New York, New York 10104-3800
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Einar Stole
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